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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/783,675	02/16/2004	James Say	TS-02-22	7215

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EXAMINER	
LAU, TUNG S	

ART UNIT	PAPER NUMBER
2857	

NOTIFICATION DATE	DELIVERY MODE
06/02/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/783,675	SAY ET AL.	
	Examiner	Art Unit	
	TUNG S. LAU	2857	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 May 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *55-69 and 73* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *55-69 and 73* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 55-67, 69 and 73 are rejected under 35 U.S.C. 102(b) as being anticipated by B. Aussedat, (A user-friendly method for calibrating a subcutaneous glucose sensor-based hypoglycaemic alarm, *Biosensors & Bioelectronics* Vol. 12. No. 11, pp. 1061–1071, 24 March 1997).

Regarding claim 55:

B. Aussedat describes a device for monitoring glucose concentration in a biological sample of a host (page 1061, ECU), the device comprising: a continuous glucose sensor that produces a data stream indicative of a glucose concentration in a host (page 1061, ECU glucose monitoring), the data stream including a plurality of time spaced sensor data points (fig. 1); and an integrated receiver that receives the data stream from the continuous glucose sensor (page 1061, ECU), wherein the integrated receiver includes a single point glucose monitor (page 1062, needle type glucose sensor), a processor (page 1062, ECU), and a computer readable memory (page 1063, wearable ECU), wherein the single point glucose

monitor is configured to receive a biological sample from the host and to measure the concentration of glucose in the sample ((page 1062,measure glucose concentration), the measured glucose concentration including a reference data point (fig. 1, max, min, etc), and wherein the computer readable memory includes instructions configured to cause the processor to process the data stream received from the continuous glucose sensor based on the reference data point (page 1064, fig. 1). determine a rate of change of the processed data stream received from the continuous glucose analyte sensor and calibrate the data stream using the glucose concentration measured by the single point glucose monitor based on the rate of change determination (page 1063-1064, monitor rate of change in fig. 1 to perform calibration);

wherein the computer readable memory includes instructions configured to cause the processor to not calibrate or recalibrate the data stream received from the continuous glucose sensor when the determined rate of change of the processed data stream received from the continuous glucose sensor deviates from a predetermined threshold (page 1064, fig. 1, beep 1 when is less than 1%, to calibrate I1, G1, I2 and G2, so when is not less than 1%, do not calibrate I1, G1, I2 and G2)

Regarding claim 56, B. Aussedat further describes wherein the integrated receiver is configured to reject a reference data point obtained

when the rate of change of the data stream is above a threshold (page 1062, ECU alarm when below or above threshold).

Regarding claim 57, B. Aussedat further describes wherein the integrated receiver includes a data matching module configured to match a reference data point to a sensor data point to form a matched data pair, wherein the reference data point and the sensor data point are obtained at substantially corresponding times, and wherein the rate of change of the data stream is below a threshold at the time the sensor data point is obtained (fig. 1).

Regarding claim 58, B. Aussedat further describes wherein the integrated receiver includes a calibration module configured to form calibration information based at least in part on at least one reference data point and at least one sensor data point, wherein the reference data point and the sensor data point are obtained at substantially corresponding times (page 1063-1064), and wherein the rate of change of the data stream in below a threshold at the time the sensor data point is obtained (fig. 1, beep 2).

Regarding claim 59, B. Aussedat further describes wherein the integrated receiver includes a conversion function module configured to create a conversion function based at least in part on at least one sensor data point, wherein the sensor data point is obtained when the rate of change of the data stream is below a threshold, and wherein the

conversion function is configured to convert the sensor data point into a calibrated data point (page 1063-1064, fig. 1, beep 2).

Regarding claim 60, B. Aussedat further describes wherein the integrated receiver includes a sensor data transformation module configured to convert at least one sensor data point into a calibrated data point, and wherein the rate of change of the data stream at the time at which the sensor data point is obtained is below a threshold (fig. 1).

Regarding claim 61, B. Aussedat further describes wherein the integrated receiver includes a calibration module configured to form a calibration set based at least in part on at least one matched data pair, the matched data pair including reference data point and a sensor data point (fig. 1), wherein the reference data point and the sensor data point are obtained at substantially corresponding times and wherein the integrated receiver includes a calibration evaluation module configured to evaluate the matched pair (fig. 1), wherein the calibration evaluation module is configured to prevent the matched data pair from influencing the calibration set if the rate of change of the data stream at the time the sensor data point is obtained is above a threshold (fig. 1, different data point).

Regarding claim 62, B. Aussedat further describes wherein the integrated receiver includes a clinical module configured to compare a first reference data point to a second reference data point to determine whether the first reference data point is clinically acceptable (page 1063-

1064, below define threshold), wherein the second reference data point is obtained prior to obtaining the first reference data point, and wherein the first reference data point is determined to be clinically acceptable if the difference between the first reference data point and the second reference data point is below a threshold (page 1063-1064, below define threshold).

Regarding claim 63, B. Aussedat further describes wherein the integrated receiver includes a clinical module configured to compare a first sensor data point to a second sensor data point to determine whether the first sensor data point is clinically acceptable, wherein the second sensor data point is obtained prior to obtaining the first sensor data point Page 1064-1065, fig. 1, 2), and wherein the first sensor data point is determined to be clinically acceptable if the difference between the first sensor data point and the second sensor data point is below a threshold (page 1063-1064. within threshold value)

Regarding claim 64, B. Aussedat further describes wherein the integrated receiver includes a stability module configured to determine whether the sensor data is stable, and wherein the sensor data is determined to be stable if the rate of change of the data stream is below a threshold at the time the sensor data is obtained (page 1063-1064m rate of change within threshold or not).

Regarding claim 65, B. Aussedat further describes measurements indicative of in vivo glucose concentration, and wherein the threshold is

set at a predetermined level (page 1061-1062, in vivo and real time detection of glucose level).

Regarding claim 66, B. Aussedat further describes measurements indicative of in vivo glucose concentration (page 1063, in vivo), the threshold is 0.25 mg/dL/min (page 1065, can detect below 70 mg/dl/min, 0.25 is less than 70).

Regarding claim 67, B. Aussedat further describes wherein the data stream comprises measurements indicative of in vivo glucose concentration (page 1063, in vivo), and wherein the threshold is 0.5 mg/dL/min (page 1065, can detect below 70 mg/dl/min, 0.5 is less than 70).

Regarding claim 69, B. Aussedat further describes wherein the integrated receiver includes an interface (page 1063, ECU with display), and wherein the user interface is configured to request additional reference data when the rate of change of the data stream is below a predetermined threshold (fig. 1, data below L2 region).

Regarding claim 73, B. Aussedat further describes wherein the integrated receiver includes an. interface configured to display continuous glucose sensor data and single point glucose monitor data (page 1062-1063, display LCD from ECU, with needle type as single point glucose monitor).

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

a. Claim 68 is rejected under 35 U.S.C. 103(a) as being unpatentable over B. Aussedat, (A user-friendly method for calibrating a subcutaneous glucose sensor-based hypoglycaemic alarm, *Biosensors & Bioelectronics* Vol. 12. No. 11, pp. 1061–1071, 24 March 1997).

Regarding claim 68, B. Aussedat further describes measurements indicative of in vivo glucose concentration (page 1061-1062), and wherein the threshold is greater than 0.5 mg/dL (page 1063, 70 mg/dl).

B. Aussedat does not talks about greater than 0.5 mg/dL/min, but talks about 70 mg/dL on page 1063, seems this limitation is personal preference to fit on a particular design requirement.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify B. Aussedat to have greater than 0.5 mg/dl/min so that a particular requirement can be made for a particular design choice.

Response to Arguments

2. Applicant's arguments with the amended claims filed 05/16/2011 have been fully considered but they are not persuasive.

A. Applicant argues in the arguments that the prior art does " Nowhere in Aussedat does it teach or suggest an integrated receiver that includes, in addition to receiving data stream from a continuous glucose sensor, a single point glucose monitor which is configured to receive a biological sample to measure glucose concentration in the sample, where the measured glucose concentration includes a reference data point" (page 8).

The ECU with glucose sensor on page 1061 appear to be "an integrated receiver that includes, in addition to receiving data stream from a continuous glucose sensor", "a single point glucose monitor (ECU with glucose sensor) which is configured to receive a biological sample to measure glucose concentration in the sample, where the measured glucose concentration includes a reference data point" on page 1063, 1064, and 1065 as show below:

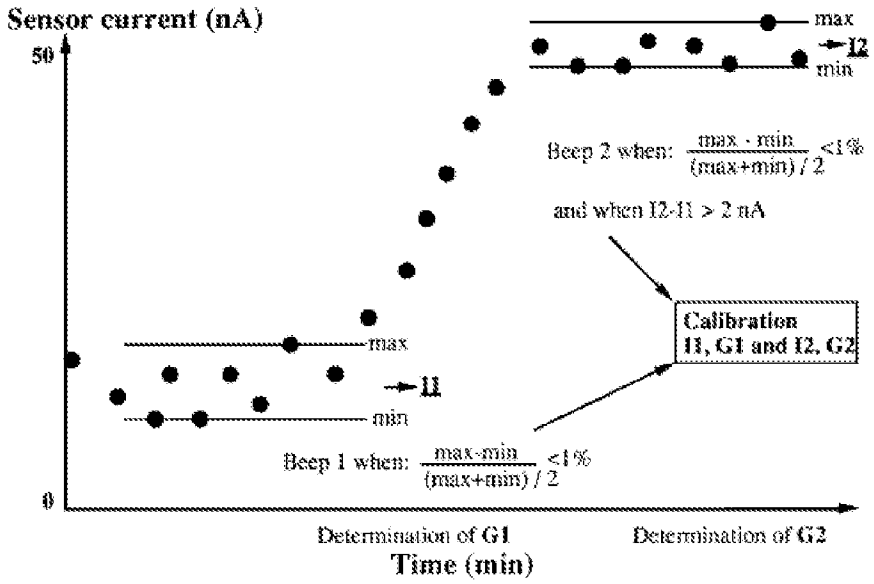

Fig. 1. Principle of the plateau recognition performed by the ECU.

B. Applicant argues in the arguments that the prior "nowhere does Aussedat disclose or suggest rejecting a reference data point obtained when the rate of change of the data stream is above a threshold (page 9). Comparing a first reference data point to a second reference data point to determine whether the first reference data point is clinically acceptable (page 10)

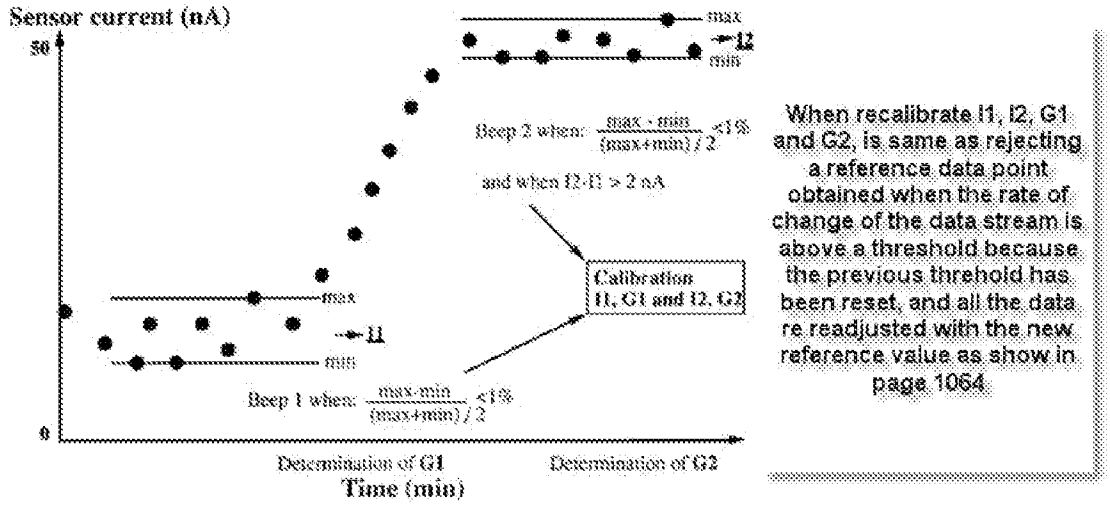

Fig. 1. Principle of the plateau recognition performed by the ECG.

Aussedat disclose Comparing a first reference data point to a second reference data point to determine whether the first reference data point is clinically acceptable on fig. 1

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee

pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Contact information

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tung S. Lau whose telephone number is 571-272-2274. The examiner can normally be reached on M-F 9-5:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Drew Dunn can be reached on 571-272-2312. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Tung S. Lau/
Primary Examiner, Art Unit 2857
May 24, 2011